

K971086

**II 510(k) Summary of Safety and Effectiveness**  
**in Accordance with SMDA'90**

B. Braun Medical, Inc  
824 Twelfth Avenue  
Bethlehem, PA 18018  
(610)691-5400

March 12, 1997

DEC 19 1997

**Contact:** Mark S. Alsberge, Regulatory Affairs Manager

**Product Name:** Radial and Femoral Artery Catheter

**Trade Name:** Wire, Guide, Catheter

**Classification name:**

Cardiovascular  
Class II, 80DQX  
21 CFR 870.1330

**SUBSTANTIAL EQUIVALENCE<sup>1</sup> TO:**

Name	510(k) number	Applicant
Arrow Radial Artery Catheter	K810675	Arrow International Inc,

**Device Description:**

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical, Inc. intends to introduce into interstate commerce a Radial and Femoral Artery Catheter. The Radial and Femoral Artery is a device that is utilized to access an artery for blood sampling and blood pressure monitoring.

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<sup>1</sup> The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

**Material:**

The Radial and Femoral Artery Catheter composed of materials that have been tested in accordance with the ISO Standard 10993 and have been determined to be suitable for the intended use of this product.

**Substantial equivalence:**

The Radial and Femoral Artery Catheter is similar in materials, form, and intended use to the Arrow Radial Artery Catheterization Kit cleared by Arrow International Inc. There are no new issues of safety or effectiveness raised by The Radial and Femoral Artery Catheter.

**Safety And Effectiveness:**

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP's.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kerry S. Hanright  
Regulatory Affairs Assistant  
B. Braun Medical Inc.  
824 12<sup>th</sup> Avenue  
Bethlehem, Pennsylvania 18018-0027

DEC 19 1997

Re: K971086  
Radial and Femoral Artery Catheter  
Regulatory Class: II (two)  
Product Code: DQX  
Dated: September 20, 1997  
Received: September 24, 1997

Dear Ms. Hanright:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, stylized 'T' and 'C'.

Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: Radial and Femoral Artery Catheter

Indications For Use:

The Radial and Femoral Artery is a device that is utilized to access an artery for blood sampling and blood pressure monitoring.

Part A  
\_\_\_\_\_  
(Division of  
Division of  
and Neurology  
510(k) Number: K971086

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)